Maine Bureau of Health

Maximum Exposure Guidelines for Drinking Water

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1.0 Overview

The Maine Bureau of Health's Environmental Toxicology Program develops Maximum Exposure Guidelines (MEGs) to assist risk managers, homeowners and others in making decisions regarding the suitability for human consumption of drinking water contaminated by chemicals.

MEGs are not promulgated by rule making and therefore are not issued as legally enforceable drinking water "standards." Rather, MEGs represent the Bureau of Health's most recent recommendations for concentrations of chemical contaminants in drinking water below which there is minimal risk of a deleterious health effect resulting from long-term ingestion of contaminated water.

The MEGs are intended to be solely health-based guidelines, and do not take into account analytical methods, treatment technology, or economic impacts. This is in contrast to the legally enforceable drinking water standards called Maximum Contaminant Levels (MCLs). MCLs are promulgated under the Safe Drinking Water Act for the purpose of regulating public drinking water supplies, and allow for consideration of the technical and economic feasibility of attaining a standard. Most MCLs are promulgated as national standards by the U.S. Environmental Protection Agency (USEPA).[1] MEGs tend to have closer agreement with USEPA Lifetime Health Advisories (HA) for chemical contaminants in drinking water, as these guidelines are primarily health based. Plots comparing current MEGs with USEPA MCLs and USEPA HAs are appended to the end of this document as Figures 1 and 2, respectively. Figure 1 shows that there is limited concordance between MEGs and USEPA MCLs, and a general tendency for MEGs to be less than MCLs. Figure 2 shows that there is good concordance between MEGs and USEPA HAs for chemicals with MEGs above 50 µg/L, but poor concordance among chemicals with lower guidelines.

The first list of MEGs was issued in 1984 as one of several criteria to be used by the Department of Human Services to determine eligibility for the waving of laboratory fees incurred with the

[1] The MCL for MTBE of 35 µg/L is an example of a MCL derived by the State of Maine.

testing of private residential water supplies for potentially hazardous contaminants.[2] The Bureau of Health last updated the MEGs in May 1990, revising existing MEGs based on new toxicological data and adding MEGs for additional compounds (Frakes, 1992).

In addition to updating existing MEGs and adding additional compounds, this January 20, 2000 revision represents a shift toward greater reliance on risk-based values. In the past, MEGs have been established as risk-based for some chemicals while defaulting either to USEPA MCLs or USEPA Health Advisories for others. The Bureau of Health is making this shift to greater reliance on risk-based values for several reasons. The Bureau believes that this approach will facilitate keeping MEGs current with changes in toxicological information. The risk-based approach will result in greater consistency across MEGs, with respect to derivation and level of health protection. This in turn will make the basis for MEGs more transparent to interested parties.

The MEGs have been derived following standard risk assessment practices and in general accordance with USEPA guidelines on development of drinking water health advisories and standards (USEPA, 1990). This methodology is summarized below. Tables listing the MEGs derived as of January 20, 2000 are appended to the end of this document. MEGs will additionally be posted on the website for the Bureau of Health's Environmental Toxicology Program (http://janus.state.me.us/dhs/bohetp/index.html). The January 20, 2000 MEG list is intended to replace all previously released MEG lists.

2.0 Procedures for Deriving Maximum Exposure Guidelines

The Bureau of Health generally uses a risk-based approach for developing MEGs. The risk assessment methods used are in general accordance with procedures described by USEPA (1990). MEGs are set to be protective of both carcinogenic effects and noncarcinogenic effects. The calculation of different MEGs for noncarcinogenic and carcinogenic effects is intended to provide the Bureau with the necessary information for recommending an MEG for a given chemical that is protective of both cancer and noncancer effects. In general, when two MEGs are calculated for a given chemical using the methods described in Section 2.1 for noncarcinogenic effects and Section 2.2 for carcinogenic effects, the lower of the two values is selected as the basis for the MEG and is considered protective of both cancer and noncancer effects.

2.1 Derivation of Maximum Exposure Guidelines for Noncarcinogenic Effects

MEGs based on noncarcinogenic toxicological effects are set at a level believed to represent a minimal risk of a deleterious effect from lifetime exposure even for sensitive subpopulations. It is assumed that noncarcinogenic effects have a threshold response (i.e., there is a dose below which toxic effects will not occur). An attempt is made to set MEGs such that total exposure will result in a daily dose below the threshold. This is believed to be accomplished through use of a *reference dose* and an allowance for *relative source contribution* of less than 100 percent.

[2] Rules Relating to Testing of Private Water Systems for Potentially Hazardous Contaminants, 10-144A CMR 233

The *reference dose* (**RfD**) is defined by the USEPA as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure level (mg/kg-day) for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is most often derived from studies of laboratory animals by application of one or more uncertainty factors for extrapolating from animal bioassay data to humans. Uncertainty factors may be applied in performing one or more of the following extrapolations: a) from a lowest-observable-adverse-effect level (LOAEL) to a no-observable-adverse-effect-level (NOAEL)[3]; b) from an acute or subchronic exposure to chronic exposure[4]; c) from responses in laboratory animals to responses expected for the average human; d) from responses for the average human to possible sensitive sub-populations; and e) for limitations in the database. These uncertainty factors typically range from 3 to 10 and are combined multiplicatively. In this way, it is not unusual for RfDs to be set 100 to 1000-times lower than the daily dose found not to cause any observable adverse effect in a animal bioassay. The value of the RfD is chemical-specific. The lower the value of the RfD, the more toxic the substance.

The *relative source contribution* (**RSC**) is the fraction of the chemical intake allowed to come from a drinking water source. Following EPA (1990) guidance, in the absence of data to estimate exposure to the chemical from other water-related routes of exposure or other sources (e.g., food), the default relative source contribution is 20%. That is, the MEG is set to allow only 20 percent of the RfD to result from ingestion of up to 2 liters of contaminated water per day. When sufficient data are available to assess the contribution of other sources of exposure, a chemical-specific RSC may be derived.[5] In accordance with EPA (1990) guidance, 80 percent is the ceiling for the RSC.[6]

In deriving MEGs it is also necessary to consider a *water consumption rate* and *body weight*. The water consumption rate (**WCR**) is the assumed total amount of tapwater consumed daily by an individual. For adults (male and female), the rate of water consumption is assumed to be 2 liters per day (EPA, 1990). A 2 L/day water intake rate is believed to represent the upper 84th percentile of intake rates among the adult population (EPA, 1999). The estimated body weight (**BW**) of the exposed individual is required in the MEG calculation since the RfD is expressed on a "per kilogram body weight" basis. The average body weight for adult males and females combined is assumed to be 70 kilograms (kg). This value is slightly less than the mean general population body weight estimated at 71.8 kg for adults 18-74 years old (USEPA, 1990). For adult females, the average body weight is assumed to be 60 kg. This is the mean body weight for adult women 18-25 years old (USEPA, 1999). The 70-kg adult general population body weight is used for all MEG calculations except for chemicals in which the RfD is based on reproductive or development effects. The 60-kg adult female body weight is used for calculating MEGs for reproductive and developmental toxicants. The latest version of the USEPA Exposure Factors Handbook recommends 2.35 liters per day for total tapwater ingestion by adults as a reasonable upper limit (90th percentile value) and a general population body weight of 71.8 kg (USEPA,

[3] Applied when the key toxicological study does not determine a NOAEL, only a LOAEL.
[4] Applied when the key toxicological study is not of chronic duration (e.g., a lifetime rodent study), but rather something shorter.
[5] MTBE, a gasoline additive, is an example of a chemical where the Bureau of Health performed microenvironmental modeling that indicated the need for a RSC of 10%.
[6] See also: Federal Register / Vol. 58, No. 20 / Wednesday, January 30, 1991 / Rules and Regulations / p. 3535.

1999). Use of these values would result in about a 13% reduction in noncarcinogenic MEGs calculated using a WCR of 2 liters per day and BW of 70 kg. A similar reduction is expected for carcinogens, though here it is necessary to also check for effects on carcinogenic potency that may have been derived using a body weight of 70 kg. The Bureau of Health is considering modifying MEGs in accordance with the USEPA (1999) recommendations for water consumption rate and body weight when the MEGs are next revised.

MEGs for noncarcinogenic effects are calculated algebraically as follows:

$$MEG = \frac{RfD \times BW}{WCR} \times RSC \qquad (eq.1)$$

USEPA maintains databases of RfDs the Agency has derived over the years. USEPA's premier database for toxicological data including RfDs is called *IRIS* (Integrated Risk Information System). RfDs listed on IRIS have undergone an Agency wide review and are viewed as USEPA's preferred toxicological data. RfDs for chemicals not listed in the IRIS database can sometimes be found in the USEPA's Superfund Program HEAST (Health Effects Summary Tables) database. USEPA's Office of Pesticide Programs (OPP) also maintains a database for RfDs and other toxicological data for pesticides. It is the Maine Bureau of Health's preference to look first to IRIS as a source for toxicological data, followed by HEAST and OPP listings. Absent toxicological data on IRIS, HEAST, or OPP databases, the Bureau of Health will consider other sources (such as the Agency for Toxic Substances and Disease Registry *Minimal Risk Levels*) or derive RfDs directly from the primary toxicity data following standard risk assessment methods.

In deriving the January 20, 2000 MEGs, the Bureau of Health has relied upon the online version of IRIS as of November 30, 1999, the 1997 Update to the Health Effects Summary Tables[7], and OPPs February 19, 1997 reference dose tracking report.

2.2 Derivation of Maximum Exposure Guidelines for Carcinogenic Effects

For chemicals classified by USEPA as *known* (also called group "A") or *probable* (group "B") human carcinogens, MEGs are derived from a quantitative estimate of the chemical's carcinogenic potency (called the *cancer slope factor*) and are set at a *incremental lifetime cancer risk* of 1 additional cancer per 100,000 population exposed.

The cancer slope factor (**CSF**) is derived by the USEPA, usually but not always, as the 95th percent upper confidence limit of the low-dose linear slope of the dose response curve and is expressed in units of $(mg/kg\text{-}day)^{-1}$. The CSF is most often derived from studies of laboratory animals, traditionally by application of dose-response models that assume no threshold for carcinogenic effects (i.e., any dose, no matter how small, will result in some risk) and allow for linearity in response at low dose. The value of the CSF is chemical-specific. The greater the value of the CSF, the greater the carcinogenic potency of the substance.

[7] Health Effects Assessment Summary Tables, US Environmental Protection Agency, Solid Waste and Emergency Response, EPA-540-R-97-036, PB97-921199, July 1997.

The incremental lifetime cancer risk (**ILCR**) is the allowable level of increased lifetime cancer risk over background rates of cancer risk. Under the assumption of a non-threshold mode of action for carcinogens, there is some increased cancer risk with any amount of exposure. Historically, federal and state standards and guidelines to limit exposure to chemical carcinogens present in environmental media and food have tended to be set at ILCR levels ranging from one in ten thousand (1×10^{-4}) to one in one million (1×10^{-6}). The ILCR associated with those chemicals for which there are federal MCLs for regulated drinking water supplies range from two in a thousand (2×10^{-3}) to less than one in a million (1×10^{-6}). As a general policy, the Bureau of Health has used an ILCR of one in a hundred thousand (1×10^{-5}) as a reference in the derivation of action levels.[8] MEGs derived by the Bureau that are based on carcinogenic effects are established at an ILCR level of one in a hundred thousand (1×10^{-5}). Note that to obtain a MEG at either an ILCR level of one in ten thousand (1×10^{-4}) or one in a million (1×10^{-6}), simply multiply or divide, respectively, the current MEGs by 10.

The algebraic equation for deriving MEGs based on carcinogen effects is:

$$MEG = \frac{\frac{ILCR}{CSF} \times BW}{WCR} \qquad (eq.\ 2)$$

As discussed above in Section 2.1, the default values for *water consumption rate* (WCR) and *body weight* (BW) are 2 liters per day and 70 kilograms, respectively.

USEPA (1990) guidance on developing drinking water regulations and health advisories sets out a different approach for chemicals classified as *possible* (group "C") human carcinogens. For these chemicals, USEPA derives health based drinking water limits following the approach described above for noncarcinogenic effects, but dividing by an additional uncertainty factor (**UF**) ranging from 1 to 10 to account for potential carcinogenicity.

$$MEG = \frac{RfD \times BW}{WCR \times UF} \times RSC \qquad (eq.\ 3)$$

The Bureau of Health departs somewhat from this policy. If a cancer slope factor is available on USEPA's IRIS database for a chemical classified as a *possible* (Group C) human carcinogen, the Bureau will use it in equation (2) to derive a MEG for carcinogenic effects. This MEG based on carcinogenic effects will then be compared to the MEG for noncarcinogenic effects calculated using equation (1) (i.e., without the added 10-fold uncertainty factor for a possible carcinogen). The lower of the two values will be used as the basis for the listed MEG. If a cancer slope factor is only available from the HEAST or OPP databases and the resulting MEG based on carcinogenic effects is substantially lower than the MEG calculated using equation (3), the Bureau will consider on a case-by-case basis using the MEG for carcinogenic effects as the listed

[8] Policy for Identifying and Assessing the Health Risks of Toxic Substances, Maine Department of Human Services, Bureau of Health , February 1988; see page 5.3.

MEG.[9] If a cancer slope factor available from HEAST or OPP results in a MEG for carcinogenic effects substantially greater than the MEG based on equation (3), the Bureau will consider on a case-by-case basis using an UF of less than 10. Otherwise, and in the absence of a CSF, the Bureau will use equation (3) applying an UF of 10 in deriving MEGs for *possible* human carcinogens.

It is worth noting that a comparison of MEGs based on equations (1) and (2) for the 55 chemicals where both RfD's and CSF's are available, indicates that use of a UF of 10 in the absence of a CSF is reasonably protective should the chemical in fact act as a nonthreshold carcinogen with low dose linearity. For about 60% of these chemicals, the ratio of the MEG based on noncarcinogenic effects (equation 1) was no more than 10-times greater than the MEG based on carcinogenic effects (equation 2). For about 80% of these chemicals, the ratio was no more than 25 (see Figure 3) while the mean value for all 55 chemicals was 7. These observations suggests that on average the use of a 10-fold UF will result in drinking water limits affording a ILCR level of around 1 in a hundred thousand or less. Only 5% of chemicals had ratios in excess of 100, suggesting that use of a 10-fold UF would only rarely result in ILCR in excess of 1 in ten thousand.

As with RfDs, IRIS is viewed as the primary database for obtaining estimates of cancer slope factors, with HEAST and OPP databases being used in the absence of an IRIS value. In deriving the January 20, 2000 MEGs, the Bureau of Health has relied upon the online version of IRIS as of November 30, 1999, the 1997 Update to the Health Effects Summary Tables, and OPPs August 25, 1999 list of chemicals evaluated for carcinogenic potential.

3.0 Departures from Standard Methods

For some chemicals, it becomes necessary or otherwise appropriate to depart from the standard methods described above. In the January 20, 2000 revisions, departures from standard methods fall into two general categories: a) chemicals with 1992 MEGs, but for which toxicity data from IRIS, HEAST or OPP are no longer (or were never) available; and b) special cases.

3.1 Chemicals with 1992 MEGs but lacking IRIS, HEAST or OPP toxicity data

The Bureau of Health has derived MEGs since 1984. For some of these previously issued MEGs, toxicity data is no longer (or never was) available from IRIS, HEAST or OPP databases. In some cases, these MEGs were based on USEPA HAs for chemicals that have since had either an RfD of CSF withdrawn from IRIS. Rather than drop these chemicals from the MEG list, the Bureau will continue to list the compounds either: 1) defaulting to a USEPA HA or USEPA Drinking Water Exposure Limit (DWEL) adjusted by the RSC term, or 2) defaulting to a Bureau of Health 1992 MEG in absence of either a USEPA HA or DWEL. The following chemicals fall under this grouping of departures from the standard methods:

[9] The MEG for Atrazine is a case in point, where the MEG based on carcinogenic effects is 3 μg/L and the MEG based on noncarcinogenic effects with the added 10-fold uncertainty factor for possible carcinogenicity is 25 μg/L.

Aluminum	Chloromethane	1,3,5-Trichlorobenzene
Ammonia	p-Chlorotoluene	Trinitroglycerol
Chloramine	m-Dichlorobenzene	2,4,6-Trinitrophenol
Chlorate	Fuel Oil	TRIS
Chlorine Dioxide	Gasoline	Ziram
Chlorite	p-nitrophenol	
Chromium (total)	Resorcinol	
Iodide	1,1,1-Trichloroethane	

It is the intent of the Bureau of Health to eventually conduct reviews of each of these chemicals. Work will be prioritized according the frequency with which the chemical is encountered as a contaminant in Maine drinking water (e.g., Fuel Oil and Gasoline are currently judged as most in need to a review of past MEGs).

3.2 Special Cases

Special cases include two groups of chemicals: a) those for which new MEGs had to be derived in the absence of IRIS, HEAST, or OPP toxicity data and consequently toxicity data were derived from either other sources or from the primary literature by BOH toxicologists; and b) chemicals for which BOH believes departures from standard methods are otherwise appropriate. All special case MEGs have a technical report describing their derivation. These technical reports can be obtained by contacting the Bureau of Health Environmental Toxicology Program. The following chemicals fall under this grouping of departures from the standard methods:

Arsenic	Ethylbenzene	Manganese	Tetrahydrofuran
m-Dichlorobenzene	4-Isopropyltoluene	Methyl Ethyl Ketone	
o-Dichlorobenzene	Lead	Methyl tert-Butyl Ether	

4.0 Designation of Status of MEGs and Future Updates

MEGs will be designated as either *Final* or *Interim*. A chemical will be designated as *Final* if toxicity data are obtained from IRIS or otherwise derived by the Bureau of Health and subject to scientific peer review and comment.[10] Otherwise, chemicals will be listed as *Interim* MEGs. The purpose of these designations is to communicate the Bureaus confidence in the toxicity data used in deriving the MEG.

Special attention is called to those chemicals where either RfDs or CSFs have been obtained from the USEPA HEAST (1997) database. A review of these chemicals for HEAST updates from the USEPA Superfund Program Office is planned. Individuals evaluating data on the presence of any of the chemicals listed below, may wish to contact the Bureau of Health about recent HEAST updates. Chemicals based on toxicity data from the HEAST (1997) database are:

[10] MTBE is an example of a chemical with a MEG (and State MCL) derived by the Bureau of Health that received outside scientific review and public comment.

1,2-Dibromo-3-chloropropane	N,N-Dimethylformamide	4-Methylphenol
1,1-Dichloroethane	Epichlorohydrin	
cis-1,2-Dichloroethylene	n-Hexane	
1,2-Dichloropropane	Methyl methacrylate	

It is the Bureau's intent that MEGs will be updated at least biennially. In between biennial updates, MEGs may be added at any time for chemicals without current MEGs. These chemicals will be posted as interim MEGs and designated as new values on the website of the Bureau of Health's Environmental Toxicology Program. During the biennial reviews, all chemicals will be checked for updates on toxicity data on USEPA's IRIS, HEAST, and OPP databases.

5.0 References

EPA. 1990. Risk Assessment, Management and Communication of Drinking Water Contamination. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA/625/4-89/024

EPA. 1996. Drinking Water Regulations and Health Advisories. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-96-002

EPA. 1999. Exposure Factors Handbook. . U.S. Environmental Protection Agency, Office of Research and Development, Washington, D.C. EPA/600/C-99/001, February 1999.

Frakes, RA. 1992. Revised Maximum Exposure Guidelines. October 23, 1992 memorandum to files. Maine Department of Human Services, Bureau of Health.

Figure 1. Comparison of MEGs and EPA MCLs

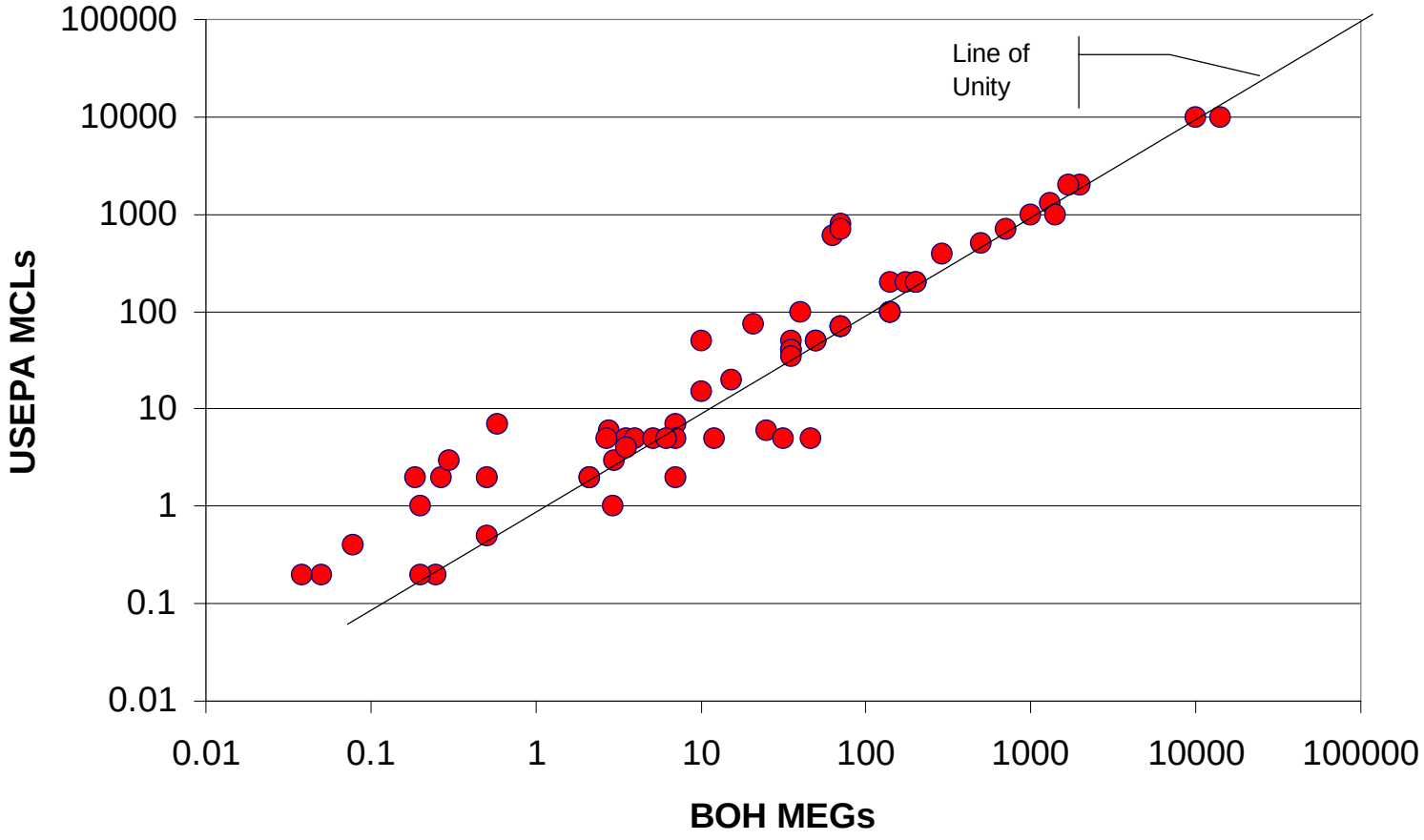

Figure 2. Comparison of MEGs and EPA Health Advisories

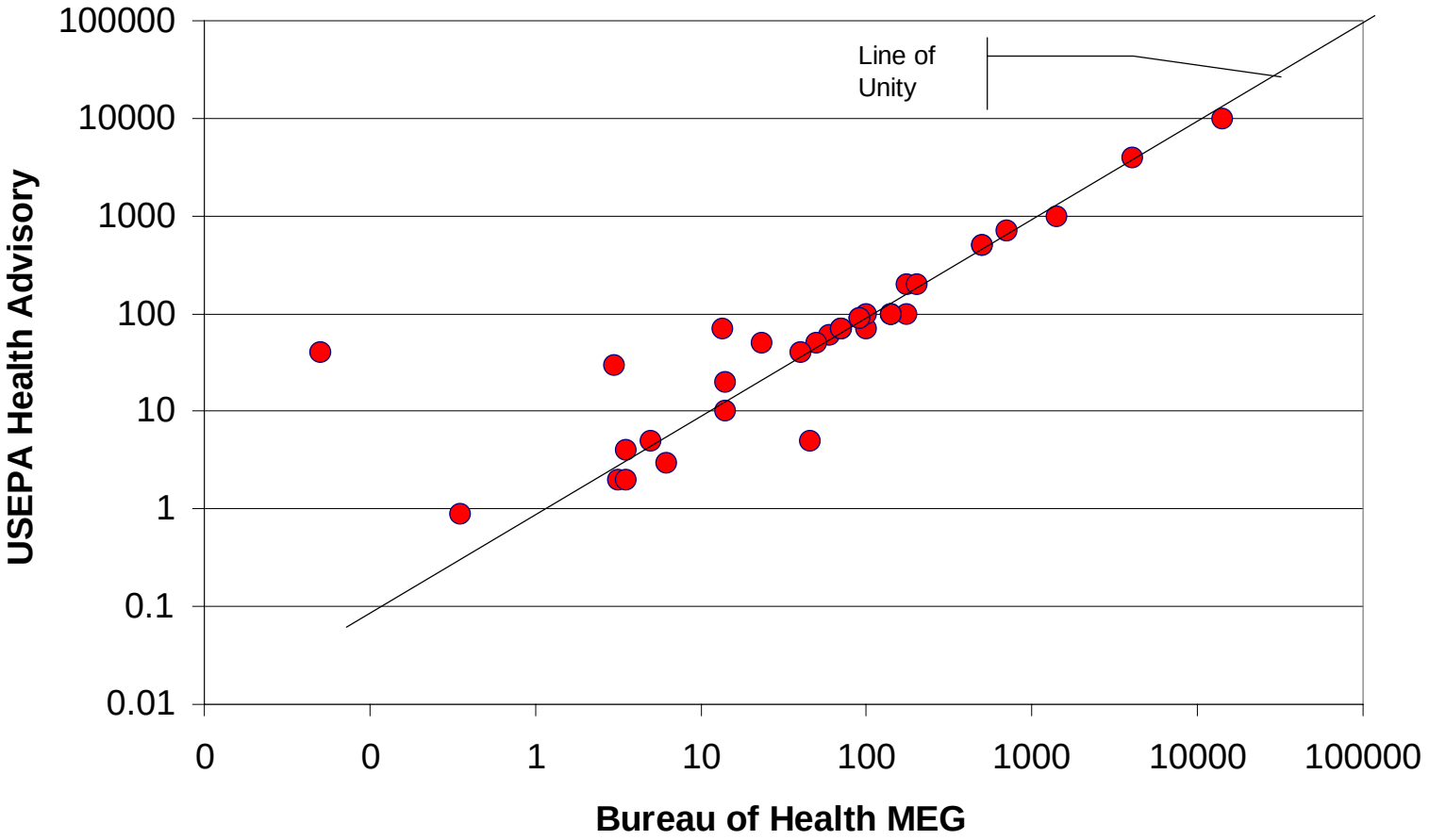

Figure 3. Comparison of Noncancer MEGs to Cancer MEGs